K08 3714

APR 15 2009

4. 510(k) Summary according to 807.92(c)

Contact: Kevin Gemas
President
866-822-7800

Titan Spine, LLC
Mequon Research Center
6140 W. Executive Drive. Suite A
Mequon, WI 53092

Trade Name: Endoskeleton® TT IBD
Product Class: Class II
Classification: 21 CFR §888.3080 Orthosis, intervertebral fusion
Product Codes: MAX
Panel Code: 87

Indications for Use:
The Endoskeleton® TT IBD is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

Device Description:
The Endoskeleton® TT IBD is comprised of a variety of implant sizes to accommodate various patient anatomy and pathology, and associated instrumentation. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI).

Predicate Device(s):
The Endoskeleton® TT IBD was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. . The four formerly Class III predicate devices include the BAK Interbody Fusion Device (Spine-Tech, P950002), Inter Fix Threaded Fusion Device (Sofamor Danek, P970015), the Ray Threaded Fusion Cage (Surgical Dynamics, P950019) and the Brantigan Cage (P960025). In addition, other Class II products including the Titan Spine Endoskeleton® TA IBD (K080615), the Abbott Spine Infix Anterior Lumbar Spacer (031672) and the Spinal Elements Lucent Interbody Device (K071724) provide features that are substantially equivalent to the Titan Spine Endoskeleton® TT IBD.

Performance Testing:
The pre-clinical testing performed indicated that the Endoskeleton® TT IBD is adequate for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Titan Spine, LLC
% Richard Jansen, Pharm. D.
13540 Guild Avenue
Apple Valley, Minnesota 55124

APR 15 2009

Re: K083714
Trade/Device Name: Endoskeleton TT Interbody Fusion Device (IBD)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 10, 2009
Received: April 13, 2009

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Statement of Indications for Use

510(k) Number (if known): K083714

Indications for Use:

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Marlene Rueckert

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083714

Concurrence of CDRH, Office of Device Evaluation (ODE)